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Washington, DC 20510–1304

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

May 29, 2019

The Honorable Norman E. "Ned" Sharpless, M.D.
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Sharpless:

As a Senator and Congressman I have literally hosted hundreds of meetings in my office. Our meeting on May 14, 2019 was one of the most disappointing and alarming meetings in my time in public service. It was my hope that we would be able to sit down and have a productive conversation about what steps you, as Acting Commissioner of the Food and Drug Administration (FDA), plan to take to reduce youth use of e-cigarettes. Instead, I walked away from that meeting with the belief that you have no intention of addressing this "public health epidemic"—as your predecessor declared it—during your tenure at the FDA.

It is my belief that any person leading the FDA—the federal agency tasked with ensuring the safety of food on our tables and medicine in our cabinets, as well as regulating the tobacco industry—must, first and foremost, feel a deep sense of responsibility to protect the health and well-being of all Americans, especially our nation's children. Unfortunately, based on our meeting, I do not have confidence that you are that leader. I write to again reiterate the specific actions that FDA should be taking, today, to protect children from a lifetime of addiction.

First, you should immediately act to ensure that flavored e-cigarettes and cigars are subject to the public health review required by the Tobacco Control Act, following the recent ruling by a federal judge striking down the 2017 decision by FDA to give manufacturers a "holiday" (in the judge's words) from that review from 2018 until 2022. Over the last year alone, our nation saw a 78 percent increase in the number of high-school children using e-cigarettes, and a 48 percent increase in the number of middle-school children using these insidious and addictive products. Today, nearly four million children are vaping. We know that kids are attracted to these products because of the kid-friendly flavors that your agency is currently, and inexplicably, refusing to regulate. You have the explicit authority to end FDA's senseless decision to suspend public health review of e-cigarettes and cigars and take action today.

We simply cannot wait another two years to crack down on these kid-friendly e-cigarette flavors, which is why I was pleased to see Judge Paul W. Grimm of the U.S. District Court for the District of Maryland rule that FDA acted illegally by delaying e-cigarette regulation. In his ruling, Judge Grimm called FDA's delay "so extreme as to amount to an abdication of its statutory responsibilities." I could not agree more. In the interest of our children's health, I strongly urge FDA not to appeal this decision and to instead act immediately—not two years from now—to regulate e-cigarette flavors.

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Next, you should demand immediate and strong enforcement of the "deeming rule." This rule, which was finalized by FDA in May 2016, prohibits any new e-cigarette product from coming to market after August 8, 2016, without FDA approval. As I have mentioned to you, and your predecessor on numerous occasions, new products are coming to market seemingly daily without FDA approval, in complete and total violation of the "deeming rule." And yet, to my knowledge, FDA has not ordered the removal of a single product for this violation.

According to JUUL's own social media posts, their popular mango and cool cucumber flavors did not come to market until 2017, and they did so without FDA approval. Based on the enclosed correspondence with JUUL, it seems clear that many of these products were not commercially available on the market as of August 8, 2016. The market is also filled with numerous JUUL look-a-like products and JUUL-compatible products. Since JUUL's popularity did not take off until after August 2016, it seems highly unlikely that all of these products were on the market prior to that date.

It defies logic that a federal regulatory agency, such as FDA, would not have an understanding of which products are on the market legally and which are on the market illegally. FDA should order the immediate removal of all e-cigarette products that were not widely and commercially available before August 8, 2016, and provide, to the public, a complete listing of all e-cigarette products and flavors that the agency believes were on the market prior to the August 2016 cut-off date. If such a list were made available, we would better be able to police products that are on the market illegally.

Finally, you must stop JUUL from claiming to be a smoking cessation device. I know from our conversation that you are impressed with a U.K. study but clearly that is an insufficient basis for rationalizing vaping as a health tool. JUUL's current marketing campaign urges smokers to "Make the switch" from cigarettes. This is, unmistakably, a smoking cessation claim from JUUL—a product that FDA has found to be largely responsible for the current epidemic of youth use of addictive e-cigarettes and which has never been approved by FDA as a smoking cessation device. In fact, JUUL has conducted zero clinical trials in the U.S. proving their products help adults quit smoking cigarettes. They should not be making this claim, and FDA has the authority to stop this deceptive marketing campaign. Use it.

President Lincoln once chastised General George McClellan for his timidity saying, "If you do not want to use the Army, I should like to borrow it for a while," and instead give the command to a general who would.

Just this month at CNBC's Health Returns conference, it was reported that former FDA Commissioner Gottlieb stated that, "we struck the wrong balance" on e-cigarettes, and noted that one of his worst days as Commissioner came last summer when he received data from the annual National Youth Tobacco Survey, which showed a massive spike in teenage use of e-cigarettes. These increases will not subside unless FDA uses its existing authority to take immediate and decisive action to regulate the kid-friendly e-cigarette flavors that are dooming our children to a lifetime of nicotine addiction.

Do not repeat the mistakes of Commissioner Gottlieb by underestimating the danger these products present to our nation's children. As Acting FDA Commissioner, you must not be a spectator to this "epidemic."

Will you use your authority to protect our children?

Sincerely,

Richard J. Durbin
United States Senator